REMARKS

Applicants acknowledge, with appreciation, the Examiner's reconsideration and vacation of the May 19, 2004 Restriction Requirement in this application.

Claims 1-78 of this application stand subject to restriction under 35 U.S.C. § 121. Initially, applicants note that they are confused by the Examiner's division of claims into six "Embodiments" which are stated to consist of various groups. A particular factor in this confusion is that Embodiments I and III contain identical claims except for one claim in each (claim 13 in Embodiment I and claim 14 in Embodiment III). Each of claims 13 and 14 recites specific antibodies. Applicants have found no guidance in the Manual of Examining Procedure ("MPEP") as to the distinction between an "Embodiment" and a "Group". Applicants are also confused by the Examiner's example of an appropriate group selection within a given Embodiment. For example, were applicants to elect the group selection of Embodiment I proposed by the Examiner, that election would appear not to fall within Embodiment I - to the extent that Embodiment includes diagnostic kits. Furthermore, such a proposed group selection might lead to the need for an inordinate number of future divisional applications.

Given this confusion and lack of guidance in the MPEP regarding Restriction Requirements of this type, applicants request further written clarification of the outstanding restriction, in the event that their elections below are other

than those deemed by the Examiner to be sufficient to allow further examination at this time.

The Examiner has divided the claims of the application into the following Embodiments:

I: Claims 4-11, 13, 15-39, 43-68, 70-71, and 74-76, as specifically drawn to a crystal of an antibody, a composition or formulation containing a crystal of the antibody, a large batch crystallization method and a diagnostic kit, classified in class 530, subclass 387.3; class 424, subclass 178.1.

II: Claims 12, 16-18, 24-30, 43-68, 70-71, and 74-75, as specifically drawn to a crystal of an anti-idiotypic antibody, classified in class 530, subclass 387.2.

III: Claims 4-11, 14-39, 43-68, 70-71, and 74-76, as specifically drawn to a crystal of an antibody, a composition or formulation containing a crystal of the antibody, a large batch crystallization method and a diagnostic kit, classified in class 530, subclass 387.3; class 424, subclass 178.1.

IV: Claims 40-42, 77-78, as specifically drawn to a method of treating a mammal by administering a crystal of an antibody or a formulation or a composition, classified in class 424, subclass 130.1.

V: Claim 69, as specifically drawn to a method of purifying a protein by affinity matrix purification, classified in class 424, subclass 130.1; class 530, subclass 413.

VI: Claims 72-73, as specifically drawn to an in vitro diagnostic method for detecting the presence of an antigen in a sample, classified in class 530, subclass 388.1, 389.1.

Applicants note that the Examiner has determined that Claims 1-3 are linking claims and would be joined with one of the Embodiments I-III, if elected.

The Examiner has further stated that if applicants elect any one of Embodiments I-IV for further prosecution, they must choose claims directed to one specific crystal of an antibody for further prosecution on the merits.

In addition, the Examiner maintains that claims 34-37 and claim 39 of Embodiments I-III are generic to a plurality of disclosed patentably distinct species comprising distinct polymeric carriers (claims 34-37) or stabilizers (claim 39). Therefore, applicants are required to elect a single species of polymeric carrier from claims 34-37, and a single species of stabilizer from claim 39, for prosecution on the merits.

Pursuant to 37 C.F.R. § 1.143, applicants elect, with traverse, the claims of Embodiment I, i.e., claims 4-11, 13, 15-39, 43-68, 70-71 and 74-76, for initial substantive examination. In addition, the applicants elect, with traverse, claims directed to a specific crystal: Infliximab crystals, for further prosecution on the merits. The claims readable upon applicant's election are claims 1-11, 13, 15-39, 43-68, 70-71 and 74-76. Finally, applicants elect, with traverse, the

species poly (amino acids) from claims 34-37 and the species sucrose from claim 39, for further prosecution on the merits. These elections are expressly without waiver of applicants' right to continue to prosecute and to obtain claims to the non-elected subject matter either in this application, or in other applications claiming priority herefrom under 35 U.S.C. § 120.

Despite the foregoing election, applicants request that the Examiner reconsider the requirement for restriction between Embodiment I and Embodiment III. Applicants believe that the claims of Embodiments I and III could be examined together without creating an undue burden on the Examiner. The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper requirement of restriction between patentably distinct inventions. The first is that the inventions must be independent or distinct as claimed. The second is that there must be a serious burden on the Examiner if restriction is not required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions". MPEP § 803.

Applicants believe that the claims of Embodiment I, as defined by the Examiner, share common elements with the claims of Embodiment III such that they may all be combined into one group for purposes of examination in the instant application. Indeed, the claims of Embodiment I and III are identical but for differences in the specific antibody crystals

claimed in claims 13 and 14. The Examiner has already addressed this issue by requiring applicants to elect one specific crystal of an antibody for prosecution on the merits in the event that generic claims covering all of the claimed antibody crystals are not allowed. In the event that one or more of the linking generic claims are allowed, applicants believe that the genus should cover all of the antibody crystals claimed in claims 13 and 14 and therefore all of the antibody crystals of Embodiments I and III.

Additionally, applicants note that the claims of Embodiments I and III relate to subject matter in the same search classifications. Finally, applicants wish to point out that the groupings proposed by the Examiner would necessitate the filing of an excessive number of patent applications and imposes a significant expense on applicants.

For all of these reasons, applicants request that the Examiner reconsider the restriction between Embodiments I and III and examine all of the claims of those Embodiments in this application. In the event that the Examiner does so, applicants stand ready to maintain their election, with traverse, of claims directed to Infliximab Crystals.

CONCLUSION

Applicants request favorable consideration and early allowance of claims in this application.

Applicants note their filing of an Information Disclosure Statement, dated June 27, 2003 and a Supplemental Information Disclosure Statement, dated August 29, 2003 in this application. Applicants request that the Examiner include initialed copies of the PTO-1449 Forms filed with those Statements with the next Official Communication.

Respectfully submitted,

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